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IMPORTANCE OF PHARMACOVIGILANCE AND OUTCOMES OF CLINICAL PHARMACY SERVICES IN INDIAN HEALTH CARE SYSTEM

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ABSTRACT

BACKGROUND: The main aim was to collect information about the adverse effects of medicines in the tertiary care hospital, to create awareness of the need for Pharmacovigilance and how this contributes to protect patients from harm, to help patients as well as health professionals to make smart therapeutic decisions. Promoting Proper awareness about the clinical Pharmacy services is needed. In future we hope that these services will promote the better patient care in India. **METHODOLOGY:** Observational cross sectional study was conducted to assess the Adverse drug reactions, for a period of six months in a tertiary care hospital in south India. For promoting better medication use, ensuring that patients receive appropriate pharmacotherapy, thus minimizing the risk of unfavorable outcomes of pharmacotherapy. Adverse drug reaction forms were collected from all health care professionals i.e., (nurses, graduates, under graduates (UG,PG), general practioners and specialists. **RESULTS:-** In Our total number of 226 Adverse drug reactions were reported by health care providers. Most of ADRs occurred with oral drugs (56.1%), followed by IV routes (13.7%) and the most common affected organ system was Integumentary system (50.6%), followed by Gastro Enterology (46%), CNS(28%). The most serious drug reactions were due to hospitalization/prolonged (68.75%), followed by life threatening (31.25%) and majority of diverse drug reactions were due to Antibiotics (19.9%), Anti-psychotics (16.8%), Chemotherapy (9.73%).Level of participation of different health-care providers Most of the reports were generated by nurses (n= 100,44.24 % of all reports), followed by under graduate students (n= 60, 26.5% of all reports),General practioners and specialists (n= 20, 8.84%). **CONCLUSION:** In our study we observe that due to inadequate knowledge gaps with regard to ADR reporting still exist among nurses, under graduate medical practioners, General practioners and specialists especially in our country where the role of pharmacists is still in transition from being product oriented to patient oriented. The study concludes that involving clinical pharmacist services in patients care can significantly helps to identify, resolve and prevent the ADRS in the hospital thereby enhancing the patient's safety.

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INTRODUCTION:**Definition of pharmacovigilance :**

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem" - As defined by WHO^[1]

AIMS OF PHARMACOVIGILANCE:

1. To improve patient care and safety in relation to the use of medicines, and all medical and medical interventions;
2. To improve public health and safety in relation to the use of medicines
3. To detect problems related to the use of medicines and communicate the findings in a timely manner
4. To encourage the safe, rational and more effective (including cost-effective) use of medicines
5. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use;
6. To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public^[2]

Roles and Benefits of a clinical pharmacist:

Clinical Pharmacist is also responsible for educating the patient about the importance of strict adherence to the medication schedule and thus enhance patient compliance.

Roles of a Clinical Pharmacist in Hospitals:

The goal of a clinical Pharmacist is to support to provide the best quality drug therapy for the patients.

These may also include :

- Prescription monitoring
- Maximize drug efficiency
- Minimize drug toxicity and promote cost effectiveness
- Therapeutic drug monitoring of drugs with narrow therapeutic index
- Drug information services
- Patient services
- Patient counseling
- Improving patient compliance collecting past medical history^[3].

BENEFITS OF ADVERSE DRUG REACTION REPORTING:

Following are the benefits of ADR reporting

1. Provide information regarding risk profile of the drug.
2. Harmonizes the risk-management activities and efforts to minimize the drug related problems.
3. Assess the safety profile of drugs, especially recently approved drugs.
4. Quantify the ADVERSE DRUG REACTIONS incidence rate.
5. Awareness development in health care professionals and patients about potential drug related problem and monitoring them to report adverse drug reactions
6. Assessment of economic impact due to adverse drug reactions and strategies to minimize the same by assessing severity and preventability^[4]

Clinical pharmacist Activities :**Before the Prescription:**

Clinical pharmacist can involve in conducting of clinical trials and also in preparation of formularies and and also in a drug information resources.

During the Prescription:

Clinical pharmacists can influence the attitudes and priorities of prescribers in their choices of treatment and he monitors ,detection and prevents the medication related problems.

After the Prescription:

Clinical pharmacist involved in counseling, Preparation of personalized formulation, drug use evaluation, outcome research, and pharmaco-economic studies standards as the hall marks.

Medication history interview:

MHI is a technique used to obtain or gather information from the patient about his medication which are used in past that includes both prescriptional and non prescriptional medication.

Clinical review:

After completion of medical history interview, the Clinical pharmacist must check where the patient is getting the appropriate dose, dosage, dosage form, duration of therapy regarding their medications which are related to their disease state

Patient counselling

The pharmacists should provide the information about condition of the patient and also educate them about the safe and appropriate use of medications.

The patient may be counselled/educated for the following points about the drugs by the Pharmacists :

- Generic name, brand name of the drug, Dosage.
- Indications/benefits of the medicine and expected action.
- Proper storage.
- How to take the medication.
- When and how long to take medication.
- Information about ceased/new medication.
- Special precautions about the drug.
- Common ADRs.
- Action to be taken when a dose is missed.
- Drugs and/or foods to be avoided. ^[5]

FACTORS CONTRIBUTING ADVERSE DRUG REACTIONS :**Multiple drug therapy:**

The incidence of adverse drug reactions has been shown to increase sharply with the number of drugs taken.

Age:

The very old and very young are more susceptible to adverse drug reactions. In general, elderly patients have multiple problems including organ failures, which can increase the incidence and severity of adverse drug reactions.

Sex:

In general, women are at greater risk of adverse drug reactions than men.

Polypharmacy:

In general, patients with more number of drugs are at greater risk of developing adverse drug reactions.

Concurrent diseases:

Patients with impaired kidney and liver functions are at greater risk for adverse drug reaction

Race and genetic polymorphism:

Hereditary aspect can be one of the factors for adverse drug reactions[6]

Role of clinical pharmacist in reporting Adverse Drug reactions:-

Now-a-days, Clinical pharmacists are getting recognized by taking part in pharmacovigilance but not only by reporting adverse drug reactions and also prevents adverse drug reactions for providing better patient care ^[7,8].

They are more involved than community pharmacist to create awareness and to decrease the risk of adverse drug reactions by frequently communicating with prescribers^[9, 10]. They create awareness by providing alert cards to the patients to avoid adverse drug reactions. Furthermore, clinical pharmacist has become a barrier between patients, public and medical related professionals^[11].

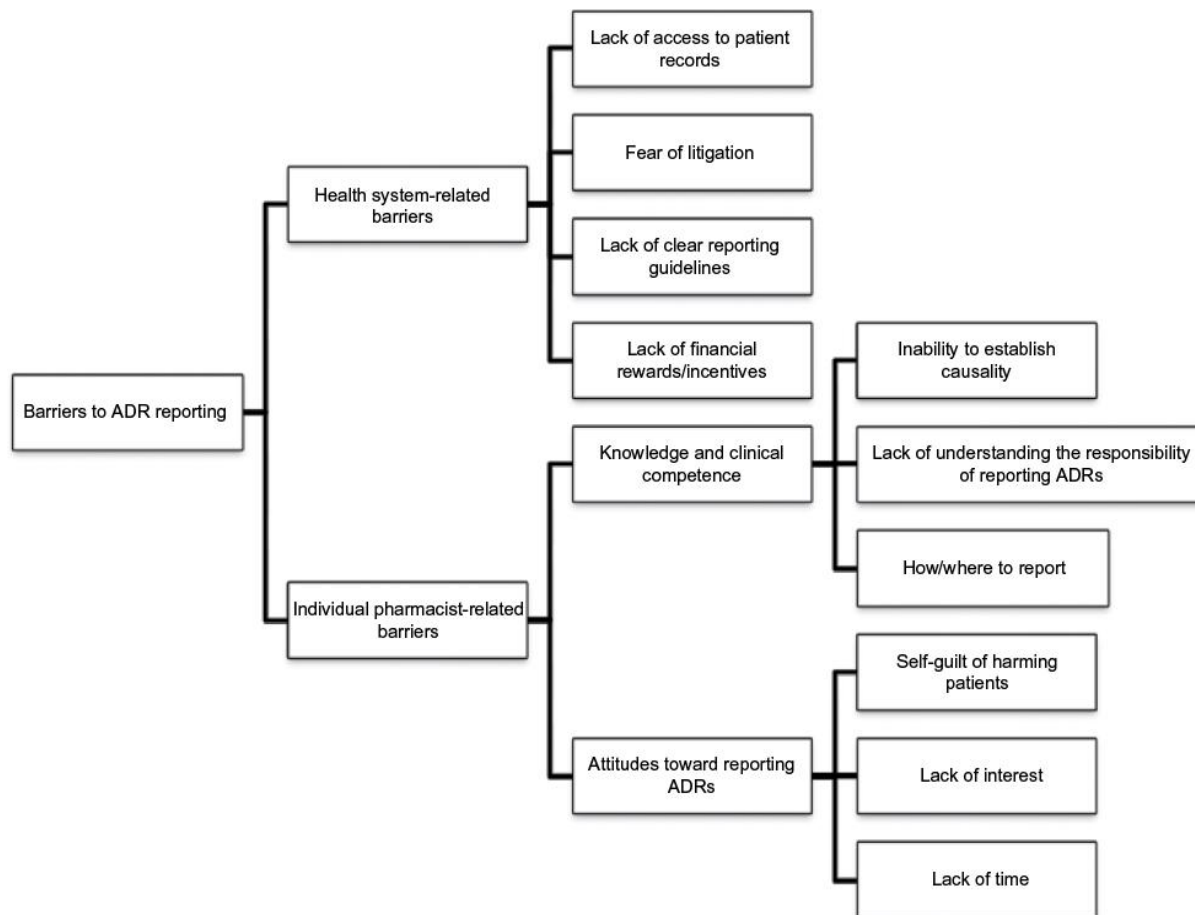


Figure 1:- BARRIERS TOWARDS ADR REPORTING EXPERIENCED BY Clinical PHARMACIST.

AIM & OBJECTIVES:

AIM:- To know the importance of pharmacovigilance and benefits of the clinical pharmacist that are involved in reporting adverse drug reactions

OBJECTIVES:

1. Educating patients to report the Adverse drug reactions directly to nearby Pharmacovigilance centres by themselves or with the help of doctors, pharmacists and make them aware about the importance of reporting adverse drug reactions
2. Programs should be conducted to get awareness of reporting adverse drug reactions to the public
3. To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.
4. Issuing Adverse drug reactions alert card to the patients.

METHODOLOGY:

Observational cross sectional study was conducted to assess the Adverse drug reactions, for a period of six months in a tertiary care hospital in south India. For promoting better medication use, ensuring that patients receive appropriate pharmacotherapy, thus minimizing the risk of unfavorable outcomes of pharmacotherapy. Adverse drug reaction forms were collected from all health care professionals i.e., (nurses, graduates, under graduates (UG,PG) general practioners and specialists.

Study design: Observational cross sectional study

Materials: Data collection forms, Alert cards, patient information leaflets (PIL)

Study site: Different departments of Government General Hospital Guntur.

Study population: People who developed an Adverse drug reactions

Study period: 6 months

Inclusion criteria:

- All the patients of both sexes who have suspected adverse drug reaction after the drug treatment from departments of Paediatrics, Gynaecology, Psychiatry, Dermatology, General Medicine, Cardiology, Neurology, Oncology.
- Healthcare members i.e. medical Interns, Nurses, were included in the study.
- Patients receiving allopathic medications from the selective departments are included in the study.

Exclusion criteria:

Patients using other than allopathic medications like ayurveda , homeopathy, Chinese or oriental medicine

RESULTS:**Table 1 : Routes Of Administration.**

S.NO	ROUTE OF ADMINISTRATION	NUMBER OF ADVERSE DRUG REACTIONS
1	Oral	127
2	Intravenous	31
3	Intra muscular	68
	Total	226

The majority of route of administration were oral 56.1% (127),intravenous 13.7% (31) Intramuscular 26.1% (68) is shown in table 1.

Table 2: Organ Systems Affected By Adverse Drug Reaction.

S.NO	ORGAN SYSTEM INVOLVED	NO. OF ADVERSE DRUG REACTIONS	PERCENTAGE (%) OF ADVERSE DRUG REACTIONS
I.	CENTRAL NERVOUS SYSTEM	28	12.4
II.	CARDIOVASCULAR SYSTEM	6	2.650
III.	EARS	1	0.44
IV.	EYES	7	3.1
V.	GASTRO INTESTINAL TRACT	46	20.4
VI.	HEMATOLOGICAL	9	3.98
VII.	HEPATO-BILLARY	5	2.21
VIII.	INTEGUMENTRY	50	22.1
IX.	METABOLIC	5	2.21
X.	MOUTH	5	2.21
XI.	MUSCULOSKELETAL	18	7.96
XII.	RENAL	6	2.65
XIII.	THROAT	1	0.44
XIV.	REPRODUCTIVE	5	2.21
XV.	RESPIRATORY	2	0.88
XVI.	OTHERS	32	14.15

It describes that Integumentry was found to be the most commonly affected organ system (50%) among which rashes and urticaria were the most common type of adverse drug reactions reported, followed by Gastro-intestinal System (46%), Central nervous system (28%), Musculoskeletal (18%),Hematological (9%) least affected was Ear, Throat (1%) and others included oedematous reactions.

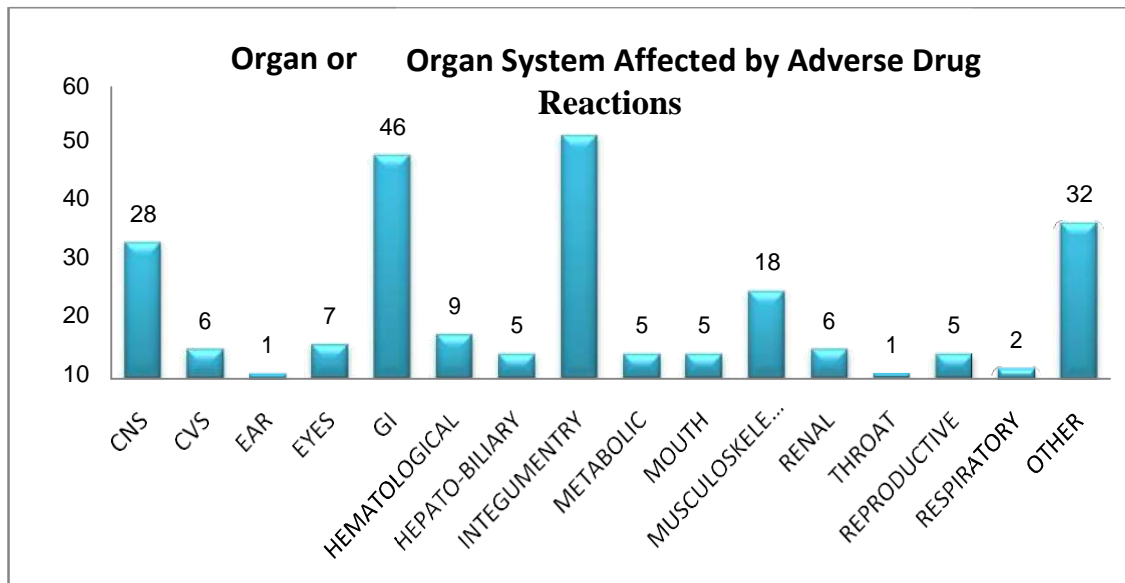


FIGURE 2: Organ Or Organ System Affected By Adverse Drug Reactions.

Table 3: Seriousness of Reaction:

CATEGORY	NO OF ADVERSE DRUG REACTIONS	PERCENTAGE OF ADVERSE DRUG REACTIONS (%)
Life Threatening	10	31.25
Hospitalization/Prolonged	22	68.75
Required Intervention To Prevent Permanent Impairment/ Damage	0	0
Others	0	0
TOTAL	32	

It shows that seriousness of the reaction majority of the Adverse drug reactions (ADR's) lead to Hospitalization/Prolonged (22%) followed by life threatening Adverse drug reactions were 10%.

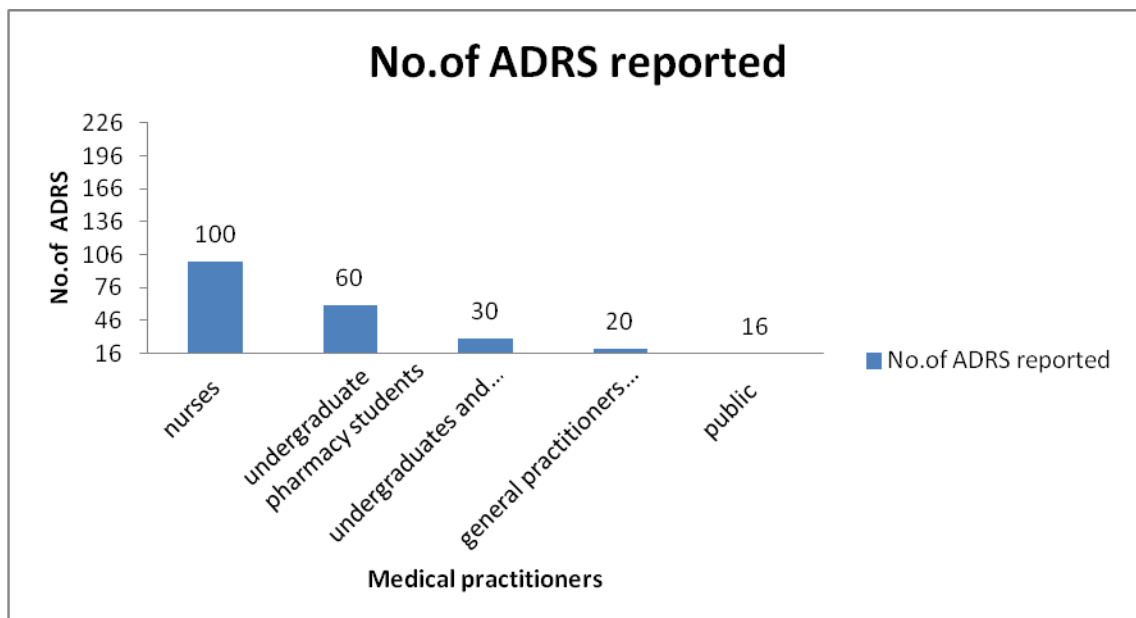


Figure 3 : level of participation of different health care providers.**DISCUSSION**

An observational cross sectional study was conducted in a period of 6 months on prevalence of adverse drug reactions and impact of educational intervention on health care members regarding Pharmacovigilance and adverse drug reporting. The most common organ systems associated with adverse drug reactions in our study were Integumentary, followed by Gastrointestinal and Central nervous system.

Antibiotics were the drug class that led to major reactions as they were mostly prescribed drugs which were similar to other studies. Majority of the adverse drug reactions were associated with oral therapy (56.19) followed by intramuscular (30.08) and intravenous (13.71%). Level of participation of different health care providers are also reported adverse drug reactions. The most important finding of this study is the significant improvement in ADR reporting after education and establishment of Pharmacovigilance Committees in care providers.

In our study we observe that there should be a Knowledge gaps with regard to ADR reporting still exist among nurses, general practitioners and specialists, under graduate pharmacy students especially in our country where the role of clinical pharmacist is still in transition from being product oriented to patient oriented. These knowledge gaps can be fulfilled through continuous professional development programs and reinforcing theoretical and practical knowledge.

CONCLUSION

Clinical pharmacy practice have a significant role internationally to expand the role of a pharmacist well beyond the traditional roles of compounding and supplying drugs. This area of practice and its development is still in infant stage in India. Need of an updated information about the diseases and drugs are supported for treating patient level problems in the community. We need to build advanced Pharmacy practice setups in every hospital in the country required to improve the standards of Pharmaceutical care and Pharmacy practices. The development of such patient benefit clinical services guidelines should be implemented in the hospitals. Across the World we hope that in future the India will be one of the strengthened country for the clinical Pharmacy services towards the patient community.

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List Of Abbreviations:

- PV : Pharmacovigilance.
- ADR : Adverse Drug Reactions.
- PIL : Patient information leaflets .
- MHI : Medication History Interview.

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